

Exhibit E

**Deposition of Daniel Bitler
January 22, 2010**

In Re:

Digitek

Daniel W. Bitler

January 22, 2010

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1 you in the phrase "product release," and,
2 again, speaking only about the years at
3 Actavis, does the term "product release" mean
4 different things in different points in your
5 inspection or investigation of a product to
6 determine if it should be released?

7 A I am not sure I understand what
8 you're asking.

9 Q That's because it was a terrible
10 question.

11 Can a product be released more than
12 one time? In other words, does "released"
13 mean only that the product is being released
14 to the marketplace or can the word "released"
15 be used more internally that the product is
16 released in some other fashion?

17 A There can be multiple release points
18 for the product during the process.

19 Q Can you tell me what those were at
20 Actavis, the release points?

21 A You would have a release of the
22 manufactured product prior to packaging.
23 There would be a release of the product
24 testing results from the laboratory. And then

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1 there would be a release of the packaged,
2 final packaged product for distribution. And
3 for certain specific customers, there would be
4 a release for shipment based off their
5 authorization.

6 Q Are you finished your answer?

7 A Yes.

8 Q Are all four of those release points
9 relevant to Digitek?

10 A Yes.

11 Q So was there a fourth release point
12 that involved someone else getting involved
13 for shipment, some other company besides
14 Actavis?

15 A Yes.

16 Q Who was that?

17 A Mylan Labs.

18 Q What did Mylan Labs have to do with
19 a release of a product for shipment?

20 A Mylan Labs provided us with
21 authorization to ship batches prior to us
22 sending them to them.

23 Q They provided some sort of blank
24 authorization that you had to fill in or they

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1 of specification but not double size?

2 A When we were going through and
3 looking at the potential root causes of how
4 double tablets could have been formed, going
5 through the discussions with manufacturing,
6 part of their process was to determine based
7 off the equipment used how it was possible for
8 double tablets to be formed. That combined
9 with the inspection process that we use as
10 part of our normal standard operating
11 procedures, it was determined that it was not
12 a variation of weights throughout a range of
13 normal specification to the double tablet; it
14 was normal spec and a couple of double
15 tablets. That was the only issue.

16 Q So manufacturing did an
17 investigation as to how it could have
18 happened, that's the root cause; right?

19 A That's part of the process, sure,
20 trying to determine what the cause was.

21 Q And QA was doing an investigation on
22 whether and how many pills were out of spec;
23 is that your testimony?

24 A It's all part of the same process.

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1 They're not separate investigations. They're
2 all part of the same investigation's process.
3 It's a step in that process.

4 Q But QA wouldn't go into the
5 equipment and try to find out if there was an
6 equipment problem; that would be the
7 manufacturing end?

8 A I mean, I did talk to manufacturing
9 and asked them to explain what they were
10 determining as part of that process. So there
11 would be conversation back and forth. But as
12 far as QA going out and working on a given
13 piece of equipment to try to ascertain what
14 took place, no. That was left to the
15 manufacturing department to make that
16 determination.

17 Q On the QA end of it -- and I
18 understand your testimony that it's one
19 investigation. But on the part that's
20 actually being done by QA people, that was to
21 determine whether there are out-of-spec
22 Digitek tablets? Is that the basic point of
23 the investigation?

24 A I'm sorry. I'm not sure what you're

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1 assurance director that the FDA was critical
2 of the failure of the quality unit to reject
3 products not meeting specifications?

4 MR. MORIARTY: Objection. This
5 is May 20. He probably wasn't even there
6 then.

7 MR. PETTIT: Please, sir, just
8 object.

9 BY MR. PETTIT:

10 Q The question was: No one ever told
11 you that?

12 MR. MORIARTY: Objection.

13 THE WITNESS: No, because
14 you're talking about in this case the
15 quality unit. That's not quality
16 assurance by itself. It's the quality
17 unit.

18 BY MR. PETTIT:

19 Q What's the quality unit?

20 A That includes quality control,
21 laboratories. When you say not meeting
22 specifications, it could be
23 laboratory-related. It could be --
24 validation's part of the quality unit. It

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1 could be validation-related. It could be
2 manufacturing. The quality unit encompasses
3 all quality systems and all quality members of
4 the organization. It's not just quality
5 assurance.

6 Q But it sure could be focused on the
7 release of Digitek tablets Lot 70924A2
8 following a visual inspection, could it not?

9 MR. MORIARTY: Objection.

10 THE WITNESS: That was a single
11 item that they were looking at was that
12 investigation.

13 BY MR. PETTIT:

14 Q So out of all of the many, many
15 products Actavis made, they made a point of
16 having an inspection that was focused on
17 something which they spelled out, and they
18 actually spelled out the name of the drug,
19 digoxin tablets, which is Digitek, the lot
20 number, the dosage, the fact that there was a
21 visual inspection. Did anyone ever tell you
22 that the FDA in this inspection was focusing
23 on your release of Digitek 70924A2 after a
24 visual inspection?